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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,864	03/26/2001	Frederick William Cain	P 279285 F.7595	6071
9629	7590	12/09/2003	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			PADEN, CAROLYN A	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/816,864	CAIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Carolyn A Paden	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13,15-22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13,15-22,24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

*Carolyn Paden*

11-24-03

The final rejection advanced in the last office action has been withdrawn and prosecution of this case on its merits continues. The terminal disclaimer has been entered

Claims 13, 15-22 and 24-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 26, 27, 29 and 30 all contain the phrase "in a weight ratio of 1:99 of said solid additive to 99:1 of said matrix" when it is clear that the claims should refer to the composition as -in a weight ratio of 1:99 to 99:1 of said solid additive to said matrix-. An amendment to the claims clarifying this issue would overcome the rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 15-22 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shefer (2003/0,152,629).

Shefer discloses a multi-component controlled release system for food products, nutraceuticals and beverages. The composition is a free flowing powder made from microspheres of an average sphere size from about 20 microns to 100 microns (column 4, column 2, paragraph 0047 to 0048), as required in claim 1. Folic acid is a nutraceutical component contemplated at page 9, paragraph 0114. The matrix is described at page 8, paragraph 0100 to include the components of claim 25. The claims appear to differ from the reference in the suggestion of the specific ratio of matrix to additive and in the suggestion of the loose bulk density of the system. The bulk density of an edible free flowing powder is described at page 1, column 2, line 5 to be at 0.5 g/cc. Thus even though Shefer does not specifically state the bulk density of their product, one of ordinary skill in the art would have expected the free flowing powder of Shefer to have a bulk density that is close to that amount shown in the prior art of about 0.5 kg/l or 0.5 g/cc. Further even though the particular ratio of matrix to additive is not shown in the reference, one of ordinary skill in the art would have expected a folic acid formulation to contain at least 1% folic acid. Even though folic acid is not specifically described as an additive, this compound is an essential nutrient and

would have been an expected additive in fortified foods. Thus it would have been obvious to one of ordinary skill in the art to utilized the formulation of Shefer as the formulation of the claims. No unobvious or unexpected result is seen to frlom from the particular ratio of folic acid to matrix particularly when recommended daily amounts of folic acid has been provided by nutritionists for a long time.

With regard to claims 26, 27 and 29 the additive/matrix system is also used to fortify products with flavor. Thus one expect the flavor of the Shefer composition to be improved.

Claims 30 and 31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is 703-308-3294. The examiner can normally be reached on Monday to Friday from 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached on (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is 703-305-7718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

*Carolyn Paden*

CAROLYN PADEN 11-24-03  
PRIMARY EXAMINER  
GROUP 1300 1761